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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,562	09/16/2003	Nina Rautonen	17031	2985

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	Layla Bland	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-16 and 26-30* is/are rejected.

7)☐ Claim(s) *7 and 17-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on - is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2003, 11/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application claims benefit to Finnish Patent Application No. FI 200321660, filed on September 17, 2003. Claims 1-33 are pending in this application and are examined on the merits herein.

Drawings

The drawings are objected to under 37 CFR 1.83(a). Page 8 of the specification includes a brief description of the drawings, but no drawings are present in the application.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The use of the trademark Raftiline has been noted in this application. It should be in all capital letters wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 7, 17-25, and 31-33 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7, 17-25, and 31-33 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 9-16 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the pH throughout the colon and increasing the amount of butyrate in the colon, does not reasonably provide enablement for treating and preventing imbalanced colon fermentation or managing lactose intolerance, food allergy, inflammatory bowel disease, or celiac disease using any carbohydrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation,

such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to the treatment and prevention of imbalanced colon fermentation using a large number of agents. Thus, the claims taken together with the specification imply that any carbohydrate can be used to prevent and treat all imbalanced colon fermentation, including anything associated with lactic acid accumulation, including such embodiments as lactose intolerance and inflammatory bowel disease.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Polydextrose is known to have physiological effects similar to those of dietary fiber, including decrease in fecal pH and increased short-chain fatty acid production. Polydextrose is known to increase *Lactobacillus* and *Bifidobacterium* species in the colon, but Hove, et al. (Am J Clin Nutr 1994; 59: 74-9) have shown that the presence of lactic acid bacteria in the colon does not change the pattern of colonic fermentation or the degree of intestinal lactose malabsorption [abstract]. In light of the teachings of Hove, et al., ingestion of polydextrose cannot be expected to treat lactose intolerance.

Known treatments for food allergy and celiac disease or limited to simply avoiding the foods which cause the problem [Merck manuals online].

The claims also encompass such embodiments as reducing the risk of inflammatory bowel disease. Inflammatory bowel disease has more than one cause (World J. Gastroenterol. 2006 Aug 14; 12(30): 4807-12, abstract) and thus the risk cannot be predictably reduced using a single type of agent.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided a working example for increasing the concentration of butyrate and decreasing the concentration of branched VFAs in healthy humans.

However, the specification does not provide guidance or working examples for the treatment of humans having lactose intolerance, food allergies, inflammatory bowel disease, celiac disease or any other condition. No guidance is presented as which amount and frequency of dosage of sustained release carbohydrates would be enough to affect a change in the above conditions.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the wide variety of conditions to be treated, the large number of possible carbohydrate agents and the high unpredictability in the art as evidenced

therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "increasing the tolerance of probiotic lactic acid bacteria." It is not understood which tolerance is meant to be increased; for the purposes of examination tolerance towards lactose is assumed. Claims 9-11 recite the limitation "facilitating the management" of certain disorders. It is not clear what is meant by "management," whether it means to reduce the severity of symptoms, or to reduce the frequency of symptoms, etc. For the purposes of examination it is assumed to refer to a reduction in severity of symptoms. Claim 13 recites the limitation "balancing or normalizing the microbial community throughout the colon." It is unclear if this means to evenly distribute microbes throughout the colon or to establish a particular ratio of different bacteria in the colon; the latter is assumed for examination purposes.

Claim 30 recites the limitation "the method according to claim 15 wherein the weight ratio of polyol to polydextrose..." Claim 15 depends from claim 14 and neither

mention polydextrose. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8, 12 and13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jie, et al. (Am J Clin Nutr 2000, 72:1503-9).

Claim 1 is drawn to a method comprising administering slowly fermented complex oligomeric or polymeric carbohydrate(s) to a subject. Claims 2 and 3 limit the carbohydrate. Claims 2-6 and 8, 12 and 13 are drawn to the method of claim 1 wherein the carbohydrate is administered in amount effective in achieving a number of other effects, including preventing the accumulation of lactic acid in the colon, reducing pH in the colon, reducing putrefactive fermentation in the colon, increasing the tolerance of

probiotic lactic acid bacteria, reducing the risk of inflammatory disease in the colon, and balancing or normalizing the microbial community in the colon.

Jie, et al. teach a study in which 4-12 grams of polydextrose per day were consumed by volunteers in order to study the physiologic effects. Fecal pH decreased proportionally to polydextrose intake. Short-chain fatty acid production (butyrate) increased with polydextrose ingestion. *Bacteroides* (infection-causing bacteria) species decreased and *Lactobacillus* and *Bifidobacterium* (lactic acid bacteria) species increased. [page 1503, Results] Jie, et al. also teach that polydextrose is partially fermented in the large intestine and fermentation of polydextrose leads to diminished putrefactive microflora and suppressed production of carcinogenic metabolites [page 1503, column 2, lines 13-19]. A high fecal output and low bowel pH can suppress the production of enteric toxins, which plays an important role in the prevention of diverticulosis and reduces the risk of bowel cancer [page 1506, column 2, lines 16-18]. Jie, et al. are silent regarding the amount of lactic acid in the colon. See In re Best, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Furthermore, the claimed composition contains the same active ingredients as that of Jie, et al. and will therefore have the same properties and effects.

Claims 14-16, 26-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger, et al. (WO 00/40101, published July 13, 2000).

Claims 14-16 are drawn to the method of claim 1, wherein the carbohydrate is administered with a carrier, specifically a polyol, in a synergistically effect amount. Claim 30 limits the weight ratio of polyol to polydextrose.

Olinger, et al. teach a dietetic chocolate composition sweetened by a composition which includes 10-90% by weight of maltitol, 9-89% by weight of lactitol and 1-55% by weight of polydextrose [page 4, lines 9-20]. The composition exhibits a surprisingly high degree of sweetness relative to what would be expected from a simple mixture of the sweeteners [page 8, lines 28-31], which shows a synergistic relationship. A specific example [page 12, Table 1, Example 4] gives a composition comprising 12.50% lactitol and 26.50% polydextrose. This is a ratio of roughly 1:2 polyol to polydextrose and therefore meets the limitations of claim 30. Olinger, et al. also teach their composition can be made from purified polydextrose, unpurified polydextrose, hydrogenated polydextrose or a mixture thereof [claim 20]. The dietetic chocolate products were tasted (administered) [page 9, lines 11-19]. It is well known that polydextrose has physiologic effects similar to those of dietary fiber (see Jie, et al. as above) and is fermented in the colon; this is an inherent property.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoebler, et al. (J Sci Food Agric 2000; 80: 1357-1364).

Claim 20 is drawn to a method comprising administering a slowly fermented complex oligomeric or polymeric carbohydrate in an amount which is effective in sustaining and controlling the fermentation throughout the colon, wherein the carbohydrate is selected from the group consisting of xanthan, alginate, and a xylooligomer.

Hoebler, et al. teach a study investigating the fermentative properties of seaweed extracts in different digestive sites of pigs [abstract]. Pigs were fed a standard diet supplemented with 40g of alginate per day for at least 5 days [page 1358, heading Animals and diets]. It was found that alginate was progressively fermented from the caecum to the colon [page 1360, column 1, lines 23-26].

Claims 1-6, 8, 12-16, and 26-28 and 30 are rejected under 35 U.S.C. 102(e) and 35 U.S.C. 102(as being anticipated by Rautonen, et al. (US 20030157146 A1, published August 21, 2003.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-6, 8, 12-16 and 26-28 and 30 teach as discussed above.

Rautonen, et al. teach a method comprising administering to a mammal polydextrose alone or in a synergistic combination with a polyol [page 9, lines 4-13]. The limitations of claims 4-6, and 8 including reducing the pH throughout the colon, etc. are met because the composition contains the same active ingredients and will therefore have the same properties and effects. The term polydextrose includes hydrogenated polydextrose which may be at least 80% pure [page 15, lines 12-23]. In one particular example, Litesse® and lactitol were added to a basal diet of rats at 2% (w/w) concentration of each [page 22, lines 11-14].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, 12-16 and 26-28 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-12, 15, 21, and 22 of copending Application No. 10/341748. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of each application are drawn to a method comprising identical compositions for different intended effects. Identical compositions are expected to have the same properties and effects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ldb

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER